

# **Exhibit 1**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

COSMO TECHNOLOGIES LIMITED, )  
VALEANT PHARMACEUTICALS )  
INTERNATIONAL, and VALEANT )  
PHARMACEUTICALS LUXEMBOURG )  
S.À R.L., )  
) C.A. No. 15-116 (LPS)  
Plaintiffs, )  
)  
v. )  
)  
PAR PHARMACEUTICAL, INC., )  
)  
Defendant. )

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COSMO TECHNOLOGIES LIMITED, )  
VALEANT PHARMACEUTICALS )  
INTERNATIONAL, and VALEANT )  
PHARMACEUTICALS LUXEMBOURG )  
S.À R.L., )  
) C.A. No. 15-164 (LPS)  
Plaintiffs, )  
)  
v. )  
)  
ACTAVIS LABORATORIES FL, INC., )  
)  
Defendant. )

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COSMO TECHNOLOGIES LIMITED, )  
VALEANT PHARMACEUTICALS )  
INTERNATIONAL, and VALEANT )  
PHARMACEUTICALS LUXEMBOURG )  
S.À R.L., )  
) C.A. No. 15-193 (LPS)  
Plaintiffs, )  
)  
v. )  
)  
ALVOGEN PINE BROOK, LLC, )  
)  
Defendant. )

**PLAINTIFFS' FIRST SET OF REQUESTS FOR  
PRODUCTION OF DOCUMENTS AND THINGS (Nos. 1-54)**

**REQUEST NO. 4**

All documents and things concerning the likelihood of FDA approval of Your ANDA Product.

**REQUEST NO. 5**

All documents and things concerning any request under the Freedom of Information Act by You or by a party acting on Your behalf concerning Uceris.

**REQUEST NO. 6**

All documents and things concerning any communications between You and any third party concerning Your ANDA, Your ANDA Product, or any other Extended-Release Budesonide Product.

**REQUEST NO. 7**

All development and supply agreements concerning Your ANDA Product, or any component or aspect thereof.

**REQUEST NO. 8**

Documents sufficient to identify each and every component of Your ANDA Product (including without limitation, active ingredients, excipients, and impurities) and the function(s) each such component serves in Your ANDA Product.

**REQUEST NO. 9**

All documents and things comprising a product specification or quality control or assurance standard guideline for Your ANDA Product.

**REQUEST NO. 10**

One hundred (100) representative samples of Your ANDA Product, and documents sufficient to identify their manufacture and storage prior to transfer to Plaintiffs.

**REQUEST NO. 11**

One hundred (100) grams of each of the excipients used in Your ANDA Product.

**REQUEST NO. 12**

All documents and things created in connection with the samples requested in Request Nos. 10 and 11, including without limitation, manufacturing records, batch records, any testing or analyses performed on the samples or the batch from which the samples were obtained or any portion thereof, and records of their transport.

**REQUEST NO. 13**

All documents and things concerning the design, development, research, or formulation of Your ANDA Product or any alternative formulations.

**REQUEST NO. 14**

All documents and things concerning any test, analysis, study, or evaluation of Your ANDA Product, including any alternative formulations, or any component thereof.

**REQUEST NO. 15**

All documents and things concerning any process or processes used to manufacture Your ANDA Product, including but not limited to, all manuals and guidelines for processes used in the manufacture of Your ANDA Product and all batch records or other batch documentation concerning any manufacture of Your ANDA Product.

**REQUEST NO. 16**

All documents and things concerning Uceris or any Extended-Release Budesonide Product relied upon or considered by You in the research, design, development, formulation, or manufacture of Your ANDA Product, including any alternative formulations, or in the preparation of Your ANDA, or any drafts or earlier versions thereof.

**REQUEST NO. 54**

Documents and things sufficient to describe Your corporate and personnel structures including, without limitation, organizational charts, from 2009 to present.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Maryellen Noreika*

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December 7, 2015  
9688590

# **Exhibit 2**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

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COSMO TECHNOLOGIES LIMITED,	)	
VALEANT PHARMACEUTICALS	)	
INTERNATIONAL, and VALEANT	)	
PHARMACEUTICALS LUXEMBOURG	)	
S.À.R.L.,	)	
	)	C.A. No. 15-164 (LPS)
Plaintiffs,	)	
	)	
v.	)	<b>HIGHLY CONFIDENTIAL</b>
	)	
ACTAVIS LABORATORIES FL, INC.,	)	
	)	
Defendant.	)	

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**DEFENDANT ACTAVIS LABORATORIES FL, INC.'S FIRST SUPPLEMENTAL  
RESPONSES AND OBJECTIONS TO PLAINTIFFS' FIRST SET OF  
INTERROGATORIES (NOS. 1-6)**

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure and Rule 26.1 of the Local Civil Rules for the District of Delaware ("Local Civil Rules"), as well as the applicable Scheduling Order (D.I. 19), Defendant Actavis Laboratories FL, Inc. ("Actavis" or "Defendant") hereby supplements its response to Plaintiffs' First Set of Interrogatories (Nos. 1-6) served by Plaintiffs Cosmo Technologies Limited, Valeant Pharmaceuticals International, and Valeant Pharmaceuticals Luxembourg S.à.r.l. (collectively, "Plaintiffs").

**GENERAL OBJECTIONS**

Actavis incorporates by reference the General Objections stated in its Responses and Objections to Plaintiffs' First Set of Interrogatories (Nos. 1-6) served on January 11, 2016. Those General Objections are incorporated by reference in each of Actavis's supplemental responses set forth below.

**SPECIFIC RESPONSES TO INTERROGATORIES**

**INTERROGATORY NO. 1:**

State whether Actavis denies infringement of any Asserted Claim of the Asserted Patents, and unless the answer is an unqualified “No,” for each such claim provide a detailed description of Actavis’s ANDA Product and the factual and legal bases for Actavis’s contention that such claim is not infringed, including, without limitation, identification of each limitation that Actavis contend is not present in Actavis’s ANDA Product, either literally or under the doctrine of equivalents, an identification of any documents, information, or tangible items that support, refute, or otherwise concern Actavis’s contentions, and any bases for any disagreement with any aspect of Plaintiffs’ Infringement Contentions, including those served on November 2, 2015, on a limitation by limitation basis.

**RESPONSE TO INTERROGATORY NO. 1:**

Actavis objects to this interrogatory as premature in that Plaintiffs have the burden of proving infringement of each patent claim. Actavis further objects to this interrogatory as requesting premature expert discovery and opinions, including claim constructions, which will be disclosed in accordance with the Court’s scheduling orders, the Federal Rules of Civil Procedure, and the Local Rules of the Court. Actavis further objects to this interrogatory as premature because the Court has not yet construed the claims of the Patents-In-Suit. Actavis further objects to this interrogatory as premature in that it seeks this information before Actavis has had an opportunity to conduct meaningful discovery, including expert discovery.

Actavis objects to this interrogatory to the extent that it requires Actavis to make a legal determination or admission as to, for example and without limitation, what constitutes infringing or not infringing “either literally or under the doctrine of equivalents.” Actavis further objects to this interrogatory to the extent it seeks the production, identification, or disclosure of information protected by the attorney-client privilege, work-product doctrine, or any other applicable privilege or immunity.

Subject to and without waiving the foregoing objections and its General Objections, Actavis preliminarily states that the claims of the Patents-in-Suit are not infringed by Actavis,



literally or under the doctrine of equivalents, at least for the reasons that the claims are invalid and thus cannot be infringed. Additionally, Actavis incorporates by reference the Detailed Factual and Legal Bases in Support of Actavis's Paragraph IV Certification for ANDA No. 205457 that U.S. Patent Nos. 7,410,651, 7,431,943, 8,393,273, 8,784,888, 8,895,064, and RE 43,799 are Invalid, Unenforceable and/or Not Infringed. Further, pursuant to Rule 33(d) of the Federal Rules of Civil Procedure, Actavis has produced or will produce or make available, subject to any applicable protective order(s), responsive, non-privileged documents to the extent they exist and can be located after a reasonable search from which the answers to portions of this Interrogatory may be derived.

Actavis is engaged in an ongoing investigation of the facts pertaining to this issue, and pursuant to Rule 26(e)(1) of the Federal Rules of Civil Procedure, reserves the right to revise, clarify and/or supplement its response.

**FIRST SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 1:**

Actavis incorporates by reference its responses and objections stated in its initial response to Interrogatory No. 1 above.

Subject to and without waiting the foregoing objections and its General Objections, Actavis responds to Plaintiffs' Initial Infringement Contentions Against Actavis, dated November 2, 2015 regarding asserted claims 1-7 of U.S. Patent No. 7,410, 651 ("the '651 patent"); claims 1-7 of U.S. Patent No. RE 43,799 ("the '799 patent"), claims 1-9 of U.S. Patent No. 8,784,888 ("the '888 patent"), and claims 1-4 of U.S. Patent No. 8,293,273 ("the '273 patent"), and Plaintiffs' Initial Infringement Contentions Against Actavis with Respect to U.S. Patent No. 9,320,716 ("the '716 patent") dated May 20, 2016 regarding asserted claims 1-10, 12-20, 22, and 24-29 as follows:

**I. Actavis's ANDA Products Do Not Infringe Claims 1-7 of the '651 Patent or Claims 1-7 of the '799 Patent**

For at least the below reasons, Actavis's ANDA Product will not infringe any asserted claim of the '651 and '799 patents, either directly or under the doctrine of equivalents.

[illegible]

[REDACTED]

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Actavis is engaged in an ongoing investigation of the facts pertaining to this issue and expert discovery has not yet begun. Pursuant to Rule 26(e)(1) of the Federal Rules of Civil Procedure, Actavis reserves the right to revise, clarify, and/or supplement its response.

**INTERROGATORY NO. 3:**

Describe in detail Actavis's decision to develop and seek FDA approval for Actavis's ANDA Product, including, without limitation, discussion of the anticipated commercial benefits of developing and obtaining FDA approval of Actavis's ANDA product, identification of the individuals most knowledgeable about the reasons why Actavis decided to develop and seek FDA approval for Actavis's ANDA Product and the circumstances leading to the submission of Actavis's ANDA, and identification of any documents, information, or tangible items that contain the reasons why Actavis decided to develop and seek FDA approval for Actavis's ANDA Product.

**RESPONSE TO INTERROGATORY NO. 3:**

Actavis objects to this interrogatory as vague, overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence in seeking "discussion of the anticipated commercial benefits of developing and obtaining FDA approval of Actavis's ANDA product" and "identification of the individuals most knowledgeable about the reasons why Actavis decided to develop and seek FDA approval for Actavis's ANDA Product." Actavis also objects to this interrogatory as vague, overly broad, unduly burdensome in asking for the identities of the persons "most knowledgeable" about the identified subject matter. Actavis also objects to this interrogatory as the undefined term "most knowledgeable" is vague and ambiguous. Actavis objects to this interrogatory to the extent it seeks the production,

Dated: July 28, 2016

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# **Exhibit 3**

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

SUPERNUS PHARMACEUTICALS, .  
INC., .  
Plaintiff, . Case No. 14-cv-06102,  
vs. . 14-cv-7272  
ACTAVIS, INC., et al., . Newark, New Jersey  
Defendants, . March 3, 2016  
And related actions. .

TRANSCRIPT OF HEARING  
BEFORE THE HONORABLE LEDA DUNN WETTRE  
UNITED STATES MAGISTRATE JUDGE

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1 (Commencement of proceedings at 10:12 A.M.)

2

3 THE COURT: Hi, we're on the record in Supernus  
4 versus Zydus, 14-CV 7272.

5 May I have counsel for those parties, please,  
6 announce their appearances.

7 MR. BATON: Good morning, Your Honor, this the Bill  
8 Baton of Saul Ewing, New Jersey counsel for plaintiff  
9 Supernus.

10 THE COURT: Good morning.

11 MR. HAUG: Also for Supernus, Ed Haug, Sandra  
12 Kuzmich, Richard Kurz, and Laura Fanelli, good morning.

13 THE COURT: Good morning.

14 And for Zydus?

15 MS. OFOSU-ANTWI: Good morning, Your Honor.

16 THE COURT: Go ahead.

17 MR. FROELICH: Good morning, Your Honor, I guess  
18 it's Zydus goes next? Joseph Froelich, from Locke Lord, and  
19 on the line with me is my partner Michael Gaertner and our  
20 colleague Carolyn Blessing.

21 THE COURT: Okay. Good morning.

22 And I know, because we began with a case management  
23 conference involving Actavis, we also have counsel for  
24 Actavis, who can go ahead and give their appearance as well.

25 MS. OFOSU-ANTWI: Good morning, Your Honor, for

1 Actavis, Eleonore Ofosu-Antwi from Connell Foley, and with me  
2 is my cocounsel Chris Sorenson from Merchant & Gould.

3 THE COURT: Good morning.

4 So Plaintiff Supernus and Defendant Zydus have  
5 submitted letters to the Court at ECF Numbers 120 and 122,  
6 respectively, regarding a dispute as to whether Zydus must  
7 produce to plaintiff samples of components that are contained  
8 in its final ANDA product.

9 The question before the Court is whether these  
10 component samples are sufficiently relevant to the issues in  
11 the case to require Zydus to produce them. The Court finds  
12 that they are.

13 Plaintiff's amended complaint in this action  
14 accuses Zydus -- Zydus's ANDA product of infringing six  
15 patents, two of which are the '248 and '580 Patents. The  
16 claims in the '248 and '580 Patents reference components of  
17 the formulation. Plaintiff will be required to provide proof  
18 of the content of those components to establish infringement.

19 While the Court agrees with Zydus that the final  
20 ANDA product is what the ultimate determination of  
21 infringement will largely be based on, it also views as  
22 relevant for discovery purposes in this case, because of the  
23 claim language, the components of that final ANDA product.  
24 Indeed, the Federal Circuit has stated in Glaxo v. Novopharm,  
25 110 F.3d 1562 at 1567 and in Abbott Labs v. Torpharm, Inc.,

1 300 F.3d 1367 at 1373, that an infringement analysis takes  
2 into account not only the ANDA product but also all other  
3 relevant evidence bearing on the product that is likely to be  
4 sold following FDA approval.

5           The samples at issue are represented to be  
6 components that are present in the final capsules of Zydus's  
7 ANDA product. Because the ingredients or contents of those  
8 components are, in turn, part of the claims on two of the  
9 patents alleged to be infringed, the component samples are  
10 relevant to an infringement analysis.

11           Of course, Zydus will be free to challenge the  
12 degree of relevance of those component samples to the final  
13 infringement decision when that time comes. It can argue,  
14 for instance, that the component samples are somehow not  
15 representative of those in the final ANDA product, including  
16 by arguing, as it now alludes to in its letter, that the  
17 component samples have degraded due to the passage of time or  
18 nonoptimal storage conditions.

19           But in the Court's view, Zydus's arguments go to  
20 the weight to be placed on the arguments Supernus bases on  
21 the component samples and not to the discoverability, per se,  
22 of those samples. Because the component samples are relevant  
23 to the issue of infringement and proportional in the Court's  
24 view to the needs of the case, the Court will require Zydus  
25 to produce them.

1 So how long does Zydus need to produce the samples?

2 MR. GAERTNER: Your Honor, it is Mike Gaertner.

3 That's -- the only issue that I have is sometimes things get  
4 caught in customs when you bring pharmaceutical ingredients  
5 from outside the United States. We will obviously  
6 instruct -- begin instructions today to have them shipped.

7 THE COURT: Okay.

8 MR. GAERTNER: I would like 14 days just to allow  
9 for that. I think even Mr. Haug would agree, we asked 14  
10 days for our tablet samples the last time around, and I think  
11 got them to him in a week. So we're hopeful that we don't  
12 need that and that we'll get them much faster than 14 days.  
13 But, again, because of logistics issues, we'd ask for that  
14 much time.

15 THE COURT: Okay.

16 Any objection from Supernus's counsel?

17 MR. HAUG: No, that's fine.

18 THE COURT: Okay. And is there an agreement on the  
19 quantity that must be produced? Or do we need to discuss  
20 that?

21 MR. GAERTNER: I recall that in the request they  
22 asked for a particular amount. Our view is that we will  
23 produce -- if we have that amount available, we'll produce  
24 it. If not, we'll produce -- we'll tell them the amount that  
25 we have and we'll produce to them half of it, and we'll keep

1 half. And we'll disclose the amount that we have --

2 THE COURT: Okay.

3 Mr. Haug, is that sufficient?

4 MR. HAUG: Yes. That sounds fine.

5 THE COURT: Okay. That's all I have.

6 Do the parties have anything else while we're on  
7 the record?

8 MR. HAUG: Not for Supernus, thank you very much,  
9 Your Honor.

10 THE COURT: Okay.

11 MR. GAERTNER: Not for Zydus, thank you,  
12 Your Honor.

13 THE COURT: Actavis?

14 ATTORNEY FOR ACTAVIS: And nothing for -- nothing  
15 for Actavis, Your Honor.

16 THE COURT: Okay. Thank you all. I'll be speaking  
17 with you soon, I'm sure.

18 UNIDENTIFIED SPEAKERS: Bye-bye.

19 (Conclusion of proceedings at 10:12 A.M.)  
20  
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Certification

I, SARA L. KERN, Transcriptionist, do hereby certify that the 9 pages contained herein constitute a full, true, and accurate transcript from the official electronic recording of the proceedings had in the above-entitled matter; that research was performed on the spelling of proper names and utilizing the information provided, but that in many cases the spellings were educated guesses; that the transcript was prepared by me or under my direction and was done to the best of my skill and ability.

I further certify that I am in no way related to any of the parties hereto nor am I in any way interested in the outcome hereof.

s/ **Sara L. Kern**

4th of March, 2016

Signature of Approved Transcriber

Date

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